ATTACHMENT 19

UNITED STATES DISTRICT COURT

NORTHERN DISTRICT OF CALIFORNIA

SURGICAL INSTRUMENT SERVICE COMPANY, INC., *Plaintiff/Counter-Defendant,* v. INTUITIVE SURGICAL, INC., *Defendant/Counter-Claimant*.	Case No. 3:21-cv-03496-VC Honorable Vince Chhabria **EXPERT REPORT OF AMANDEEP MAHAL, MD** Complaint Filed: May 10, 2021

Highly Confidential – Subject to Protective Order

TABLE OF CONTENTS

I. QUALIFICATIONS

1. I am a board-certified obstetrician and gynecologist. I am also a board-certified female pelvic medicine and reconstructive surgeon, commonly referred to as a Urogynecologist. I am currently practicing medicine in Omaha, Nebraska.

2. I attended Creighton University School of Medicine and graduated with my medical degree in 2010. I completed residency training in obstetrics and gynecology at the University of Iowa in 2014. I completed my fellowship training in urogynecology at Stanford University in 2017. I also completed additional training through the American College of Surgeons in fundamentals of laparoscopic skills.

3. I have received numerous accolades and awards as a result of my work in the medical field, such as best research awards at national meetings, grant awarded research, and work as a sub-investigator on pivotal trials. I hold several memberships to professional medical organizations including the American College of Obstetricians and Gynecologists, American Urologic Association, American Urogynecology Society, and the Society for Clinic Research Sites. I have authored or co-authored numerous publications in national peer-reviewed journals, including Menopause, Female Pelvic Medicine and Reconstructive Surgery, and the American Journal of Obstetrics and Gynecology. I have also presented my findings at several national meetings of pelvic floor surgeons, such as American Urogynecologic Society, American Urologic Association and Society for Gynecologic Surgeons. I have held multiple teaching positions, including adjunct teaching positions with Creighton School of Medicine and University of Nebraska.

4. I began my surgical career with traditional (open) and laparoscopic surgical techniques, both of which I still currently employ. Throughout my training and career, I have been

exposed to, developed, and routinely apply surgical skills in open and laparoscopic techniques for a variety of surgical procedures, such as reconstructive pelvic surgery.

5. Beginning in 2010, I started utilizing Intuitive's da Vinci robotic surgical systems in surgical procedures, using the S and Si models at that time. I underwent training through online course work from Intuitive for safety. I have participated in several masters courses for surgery including robotic surgery, and further including hands-on courses at Intuitive headquarters in Sunnyvale, California as part of my training. Since 2010, I have performed over 1,000 robotic-assisted surgeries using various Intuitive da Vinci surgical systems including the S, Si, X, and Xi models. Examples of da Vinci robotic-assisted surgeries I have performed include hysterectomies, bladder fistula repair, prolapse repairs including uterosacral suspensions, hysteropexies and sacrocolpopexy.

6. I currently practice medicine at a private surgery center where I am an owner and partner along with other practicing urologists and urogynecologists. On average I perform 100 to 150 surgeries in a year using Intuitive's da Vinci robotic surgical systems. I hold teaching positions at the University of Nebraska Medical Center as faculty in the departments of Urology and Obstetrics and Gynecology. Through my teaching roles I oversee and instruct gynecology and urology residents on patient selection, appropriate use, set up, and surgical use with da Vinci robotic surgery.

7. Currently I hold the office of American Medical Association Nebraska alternate delegate for proceedings of the AMA. Through my position at the American Medical Association, I routinely contribute to the advocacy council on public safety.

8. A copy of my current *Curriculum Vitae* is attached to this Report at Attachment 1.

II. PRIOR TESTIMONY AND PUBLICATIONS

9. In the past four years, I have not testified as an expert witness. I was deposed and testified as a non-party witness in a case in 2021 relating to the care of a patient.

10. A list of all publications I have authored or co-authored during the past ten years is included in my *Curriculum Vitae*, attached at Attachment 1.

III. ENGAGEMENT AND COMPENSATION

11. I am submitting this Report at the request of Haley Guiliano LLP, counsel for Surgical Instrument Service Company, Inc. ("SIS"), the named plaintiff in the lawsuit captioned on this Report's first page. This Report sets forth opinions I have formed about which I may testify if called as a witness at the trial of this lawsuit.

12. I am an independent physician with extensive experience performing laparoscopic surgery as well as surgery using the da Vinci Surgical system and EndoWrist instruments marketed by Intuitive Surgical, Inc. ("Intuitive"). I have been asked to provide opinions about the use of da Vinci Surgical systems and associated instruments such as EndoWrist instruments in surgery ("da Vinci surgery") from the perspective of an experienced practicing surgeon. I have also been asked to provide opinions about laparoscopic and open surgical procedures and the instruments used in those procedures, from the perspective of an experienced practicing surgeon.

13. The facts and data I considered in connection with forming my opinions are identified in the body of this Report and listed in Attachment 2.

14. I am being compensated for my time spent in preparing this Report at an hourly rate of $400. If asked to testify in this lawsuit, I will be compensated at an hourly rate of $600 for deposition testimony and an hourly rate of $600 for testifying at trial. My compensation does not depend on the outcome of this matter.

IV. SUMMARY OF OPINIONS

15. Traditional laparoscopic surgery and da Vinci surgery are now common techniques for performing a variety of minimally invasive surgical procedures. Each of these techniques uses small incisions and a camera inserted through the incision, but they are not equivalent. For most procedures where both techniques are available, da Vinci surgery provides a number of advantages over laparoscopic surgery.

16. When comparing laparoscopic to da Vinci surgery, in my experience surgeons are primarily interested in the safety of the patient and the relative difficulty of performing procedures, and are generally less concerned with the costs of the surgical procedure to the patient or hospital. Surgeons who use da Vinci systems have the ability to and often do require that da Vinci systems are used for particular surgeries.

17. As between da Vinci Si and da Vinci Xi systems, for most surgeries a da Vinci Si system performs similarly to a da Vinci Xi system, provides similar advantages over traditional laparoscopic surgery, and is equally safe for patients and operating room staff.

18. From a surgeon's perspective, corresponding Si and Xi EndoWrist instruments are functionally similar. Although there are improvements to the da Vinci Xi robotic system compared to the Si system, once an instrument is properly located within the operating field, the operation and responsiveness of an Xi EndoWrist instrument is functionally similar to an Si EndoWrist instrument.

19. Surgical instruments can and do fail during laparoscopic surgery and during da Vinci surgery. All instruments have risks of failure, new or otherwise. EndoWrist instrument failures during da Vinci surgeries are almost always identified by the surgeon, not the da Vinci system, and are mitigated by the surgeon, usually without incident. Indeed, the process for

identifying and replacing a failed EndoWrist instrument is virtually identical to that used in traditional laparoscopy.

20. Certain "failures" identified in an Intuitive list of types of EndoWrist device failures[1] rarely occur or do not raise patient safety concerns during surgery. Other failures on the list are of types that are immediately noticeable and require either correcting the malfunction or replacing the instrument, which is a relatively simple and standardized procedure that is regularly performed during da Vinci surgery. None of the EndoWrist failures that I have experienced during a da Vinci surgery has resulted in injury to a patient or others in the operating room.

21. The use counter of an EndoWrist instrument does not provide a surgeon with any practical, relevant information about the instrument's actual usage, whether in a particular surgery or over the life of the instrument.

22. The hospitals where I operate, like other hospitals, use both new instruments and instruments that have been serviced by the hospital or a third party (*e.g.*, repaired or refurbished) to reduce costs. As a surgeon with extensive experience in traditional laparoscopic surgery, I am comfortable operating with laparoscopic instruments that have been serviced, and I am generally unable to tell the difference between a new instrument and one that has been serviced.

23. I trust the procedures of the hospitals in which I operate for supplying well-functioning, sterile instruments. Based on my years of experience performing da Vinci surgery, and having experienced failures even of new EndoWrist instruments during surgical procedures, I would feel comfortable using serviced EndoWrist instruments including those where the service

[1] Intuitive-02066979 at 7025-047

involved resetting its use counter, just as I am comfortable using serviced traditional laparoscopic instruments.

24. I reserve the right to supplement or amend this Report and my opinions in the event additional facts or other information become available.

V. TUTORIAL: TRADITIONAL LAPAROSCOPIC SURGERY AND DA VINCI ROBOTIC-ASSISTED MINIMALLY INVASIVE SURGERY

25. I may present a tutorial explaining, comparing, and contrasting traditional laparoscopic surgery and da Vinci surgery.

26. Minimally invasive surgeries, which include da Vinci surgeries and traditional laparoscopic surgeries, have increased dramatically in recent years. A recent paper that I reviewed demonstrated a more than 400% increase in the use of minimally invasive surgery training cases by general surgery residents in the years between 2000 and 2018.[2]

27. Minimally invasive surgery is a technique allowing a surgeon to access the inside of a patient's abdomen, chest, joint space, the renal/urinary system, gynecological system, and other areas of the body without having to make large skin incisions. Minimally invasive surgery can be performed using traditional hand-held laparoscopic instruments, with a single view camera to visualize the operative field. With this, a surgeon or assistant holds a small camera on a thin fiber optic cable setup to see inside the body. Additional body sites are then equipped with ports to pass instruments used in the surgery, and in some instances implants, into and out of the body. Using physical examples, photographs and/or illustrations, I may describe and explain examples of different types of traditional laparoscopic instruments and how they work .

---

[2] Bingmer et al., *Decline of Open Surgical Experience for General Surgery Residents*, Springer Nature, May 29, 2019, https://doi.org/10.1007/s00464-019-06881-0.

28. Traditional laparoscopic surgery has been commonly used in medicine for at least the past 40 years. This technique became popular for providers given the smaller incisions and decreased post-operative pain for patients, the decreased risk of infections, and the decreased length of hospital stay for equivalent surgeries when performed by laparoscopic techniques rather than open surgical techniques.

29. Given the benefits of traditional laparoscopic techniques compared to open surgical techniques, there has been a substantial push to utilize traditional laparoscopy wherever possible. This has resulted in more complex surgeries requiring finer movements within the small incisions available for such surgeries. Even with the development of additional and improved specialized instruments and procedures for traditional laparoscopy, traditional laparoscopic surgery can be physically burdensome for the surgeon and hospital support staff. In order to have two working laparoscopic instruments and a view of the surgical field with a laparoscopic camera, two persons must be present at the bedside. This is typically a surgeon and an assistant. Both individuals must hunch and bend to achieve a safe view of the operative field and also to keep the stiff laparoscopic instrument shafts pointed into the field. Once this is achieved, the dissection and work of the surgery is accomplished through small wrist movements and manipulation of the laparoscopic instruments' handles. As a surgeon fatigues during the course of a case, body posture may begin to falter, resulting in both an occupational hazard for the surgeon and staff and potential danger for the patient.

30. Da Vinci robotic-assisted surgery was a significant development in performing minimally invasive surgery and has become an essential "must-have" feature for hospital and surgical center operations over the last two decades. As described in more detail in the following section, da Vinci systems provide substantial advantages over traditional laparoscopy, such that

minimally invasive surgery can be performed by more surgeons, surgeons and operating room personnel can perform more minimally invasive surgeries with less physical strain, and minimally invasive surgery can be performed for procedures that were previously thought not possible or very difficult to perform with traditional laparoscopic equipment and techniques.

VI. COMPARISON OF TRADITIONAL LAPAROSCOPIC AND DA VINCI ROBOTIC-ASSISTED MINIMALLY INVASIVE SURGERY

31. Da Vinci surgery is a novel and unique iteration of minimally invasive surgery techniques, and provides substantial advantages over traditional laparoscopic surgery. Da Vinci systems improve upon and further a surgeon's ability to operate safely, to perform minimally invasive surgery with less strain and fatigue, and to utilize minimally invasive techniques in additional surgical situations.

32. Traditional laparoscopic surgery and da Vinci robotic-assisted surgery are not equivalent. For example, certain procedures such as radical prostatectomy are almost exclusively performed by da Vinci surgery. This is largely due to the very demanding technical needs of this surgery when nerve sparing dissection and reconstruction of the urethra is required. While possible with traditional laparoscopy, the advantages of the da Vinci system allow dissection to be performed by more surgeons in more situations, and for most surgeons with more precision. At least some of these advantages are discussed below.

33. Like most surgeons who perform minimally invasive surgery, I have had extensive training on da Vinci systems, including in medical school, my residency position, my fellowship training, and additional seminars and hands-on training sessions. I understand that da Vinci systems are provided to many medical schools at a reduced or minimal cost. Moreover, Intuitive sponsors numerous seminars and training sessions, a number of which I have personally attended. Experienced surgeons typically perform a hundred or more da Vinci surgeries a year. Some, like

myself, also have the ability to perform traditional laparoscopic surgeries, but prefer using da Vinci systems for minimally invasive surgeries. Indeed, some surgeons have gone to offering only RAS and would convert to open surgery if there was in issue during the procedure. IN such instances, laparoscopic surgery would not be an option.

34. The numerous functional advantages of da Vinci surgery over traditional laparoscopic surgery are such that even surgeons who are capable of performing both da Vinci surgery and traditional laparoscopic surgery do not consider these two techniques interchangeable. The following are some examples of features of da Vinci surgery that are not available in traditional laparoscopic procedures:

a. Da Vinci surgery takes advantage of a surgeon's stereoscopic vision and utilizes two lenses attached to a single instrument to provide for vision of the surgical field. This enables a surgeon to perceive a three-dimensional landscape of the surgical site. In traditional laparoscopy, only one point of view is used, giving a less robust two-dimensional view of the operative field.

b. Da Vinci surgery provides significantly improved ergonomics compared to traditional laparoscopy. In traditional laparoscopic surgery, a surgeon stands over the patient and manipulates hand-held laparoscopic instruments inserted into the patient through ports at the surgical site. This requires the surgeon to bend, twist, and contort his or her arms, hands, and body to accomplish tasks including dissection, cauterizing, excising, and suturing, often for several hours. In a da Vinci surgery, in contrast, robotic arms of the da Vinci robot hold the camera apparatus and all instruments relative to the ports and the patient and control the operations of EndoWrist instruments. The surgeon performing the surgery sits comfortably at

a console and moves simple controls to control the movement and operation of the EndoWrist instruments within the surgical site to perform similar tasks to those traditionally performed by laparoscopic instruments.

c. Because operating room staff and the surgeon do not need to hold or manipulate the camera and instruments during a da Vinci surgery, these common fatigue-inducing requirements of traditional laparoscopic surgery – which can cause inadvertent movement of the cameras and instruments – do not impact a da Vinci surgery. To the extent a surgeon working at the console of a da Vinci system experiences shaking or tremors, the da Vinci system minimizes or eliminates this undesired movement so it does not similarly affect the EndoWrist instruments.

d. Traditional laparoscopic instruments often have a working end within the abdomen that has limited wrist movement or ability to manipulate to accommodate patient anatomy. In contrast, most EndoWrist instruments have a "wrist" that can be manipulated about multiple axes such as roll, yaw, and pitch. Thus, in a da Vinci surgery it is less likely for an instrument to be located in a manner such that it is difficult to perform a desired task.

e. When performing a traditional laparoscopic surgery, the instruments work though a port that acts as a fulcrum. If the surgeon moves his or her hand to the right, the tip of the instrument within the incision moves to the left, and vice-versa. With practice, surgeons adapt and accommodate to this "mirrored" frame of reference compared to the surgeon's movements. In a da Vinci surgery, however, the hand motions of the surgeon directly match the desired motion of the instrument,

eliminating or greatly decreasing a surgeon's need to compensate for this unique challenge of traditional laparoscopy.

f. The optic lenses of a da Vinci system offer a magnified or "zoomed-in" view for better visualization. Combined with the increased precision due to scaled movement of a da Vinci robot arm and instruments – for example, a three-inch movement of the controls at the surgeon's console may move the instrument one inch – a surgeon has improved fine motor control relative to laparoscopic surgery.

35. In addition to the above-stated functional differences and advantages of da Vinci system, in a da Vinci surgery I can safely perform complex procedures with less skilled or experienced operating room assistants, who are not required to hold instruments or cameras during the operation.

36. In view of its advantages, da Vinci surgery has become so popular in training and in practice, it is now a standard of care for many procedures. For example, a retrospective study published in the *Journal of the American Medical Association* ("JAMA") showed that robotic surgery may represent almost one out of five general surgery procedures in the state of Michigan.[3]

37. da Vinci surgery has become a staple and essential for many surgeons. As robotic surgery has become more prevalent at many training centers in the United States, many doctors find that they require a da Vinci system to consistently complete surgeries safely. Many smaller hospital systems have at least one da Vinci system, as most surgeons who perform minimally invasive surgery would not consider working in a facility that was not able to perform a da Vinci

---

[3] Sheetz at al., *Trends I the Adoption of Robotic Surgery for Common Surgical Procedures*, Journal of American Medicine, Jan. 10, 2020, https://jamanetwork.com/journals/jamanetworkopen/fullarticle/2758472.

surgery. This is particularly true for surgeons who entered the profession within the last 15-20 years. For example, in rural Nebraska where I practice, many smaller hospitals obtain da Vinci systems to recruit and retain general surgeons.

38. Even though I am adept at traditional laparoscopy, there are surgeries that I would only perform with da Vinci surgery. For example, while sacrocolpopexy surgery can be performed laparoscopically, dissection over the great vessels and delicate internal structures such as the ureters is safer with the more precise movement and better optics afforded by the da Vinci system. Over the past three years none of the sacrocolpopexy surgeries I performed was done using traditional laparoscopy for these reasons.

39. In my experience, when comparing laparoscopic to da Vinci surgery, surgeons are primarily interested in the safety of the patient and the relativity difficulty of performing procedures, and are generally less concerned with the costs of the surgical procedure to the patient or hospital. Surgeons are generally unaware of the costs of particular procedures, or the relative cost of a laparoscopic procedure versus a da Vinci surgery.

40. In my experience, surgeons who are trained to perform da Vinci surgeries have the ability to request that surgeries are performed with da Vinci systems rather than using traditional laparoscopy. Surgeons in fact regularly demand that a da Vinci system is made available to perform particular surgeries, and in my experience hospitals acquiesce to such demands. Some surgeons may even delay a case or schedule cases at odd times in order to gain access to a da Vinci system rather than performing the procedure laparoscopically.

41. Based on my conversations with patients and my general understanding from others in the profession, patients consider whether hospitals are keeping up with current trends in technology and medicine when deciding on care. With each passing year, robotic surgery becomes

more publicly known both through hospitals' promotion of their da Vinci surgery programs and through general media or word of mouth. Accordingly, there is a sense among both hospital staff and patients that an active da Vinci surgery program is a *de facto* requirement for a hospital to be up-to-date with current trends. Patients often arrive at initial consultations with a predisposition to having a da Vinci surgery over a laparoscopic procedure. When patients are presented with an option for da Vinci surgery or laparoscopic surgery, almost all patients choose da Vinci surgery.

VII. Si SYSTEMS AND Xi SYSTEMS AND INSTRUMENTS HAVE SIMILAR OPERATIONAL PRINCIPLES, AND ARE USED FOR SIMILAR PROCEDURES

42. As between da Vinci Si systems and da Vinci Xi systems, for most surgeries a da Vinci Si system performs similarly to a da Vinci Xi system, provides similar advantages over traditional laparoscopic surgery, and is equally safe for patients and operating room staff.

43. From a surgeon's perspective, corresponding Si and Xi EndoWrist instruments are equivalent. For most Si instrument types, there is a corresponding Xi instrument of the same type. Corresponding Si and Xi instruments will have a virtually identical end effector, such as a grasper, forceps, scissor, scalpel, or the like. Corresponding Si and Xi instruments will have a virtually identical range of motion, such as available roll, pitch, and yaw movements and gripping or cutting force. Indeed, a surgeon who is experienced using Si instruments could operate a corresponding Xi instrument without issue or additional training specific to the Xi instrument.

44. Even EndoWrist instruments that are unique to the Xi system function in a substantially similar manner to Si instruments, for example, with similar available motions such as roll, pitch, and yaw, and actions such as grasping or cutting. A surgeon who is experienced using Si instruments could operate almost any Xi instrument that performs a similar function without additional training specific to the Xi instrument.

45. Although there are slight differences in the controls at an Si console versus an Xi console, the principles of operation and general user interface are substantially similar, such that the surgeon's actions to control the motion of the instrument end effector of an Xi EndoWrist by an Xi console is almost identical to the surgeon's actions to control the motion of the instrument end effector of an Si EndoWrist at an Si console. A surgeon who is trained only on an Si system could accurately control the end effector of an Xi end effector at an Xi console without specific Xi training.

46. Although there may be slight differences in the available range of movement of the EndoWrist instruments by the robotic arms in Xi systems versus Si systems, both systems provide instrument movement that is smooth and reproducible, and that provides granular control of dissection, suture placement, and resection depending on the surgery.

47. Da Vinci surgery, for both Si and Xi systems, is performed by a surgeon with the aid of a da Vinci system robot, but is not performed autonomously by the da Vinci system robot in any significant manner. Da Vinci instruments attach to respective arms of the da Vinci system robot, while the surgeon controls the robot arm to position, move, and operate the attached EndoWrist instruments. The use of the da Vinci system and operation of the robot arm assist a surgeon in more precisely positioning, moving, and manipulating an EndoWrist instrument, but all such actions are ultimately directed by the surgeon's actions at the da Vinci system console. In other words, a properly operating da Vinci surgical system does not do anything unless and until the surgeon directs the system to do something.

48. The placement of ports and the EndoWrist control box have slight variations between Si and Xi, but in my experience this does not affect the EndoWrist instrument usage in any substantial manner.

49. There are some specific differences between the Xi and Si systems. For example:

a. An Xi system has a larger potential operative field than an Si system. This field of view is helpful when operating in multiple quadrants of the abdomen in the same surgery and decreases the likelihood of instrument collision.

b. The process of bringing the robotic console to the patient bedside and attaching it to the inserted ports, known as docking, has been improved with the Xi platform. The boom, or adjustable arm that suspends the control arms of the robot, can be moved to the bedside from various positions, with easier patient access during the procedure when needed.

c. The Xi platform has the ability to accommodate movement of the patient table while operating.

50. Neither Si instruments nor Xi instruments provide any form of useful feedback related to the operation of the instrument such as haptics or force feedback. Rather, the primary form of "feedback" is the surgeon observing movements of the instruments on the da Vinci's operator video screen, as relayed by the camera, and mentally associating motions made on the surgeon's console with corresponding movements viewed via the camera.

51. Most surgeons do not change procedures or surgical plans for EndoWrist usage based on whether the surgeon is using an Si system and EndoWrists or an Xi system and EndoWrists.

52. In view of the above similarities and differences, the vast majority of procedures that are performed with an Xi system and EndoWrists can be performed with an Si system and EndoWrists without any reduction in patient safety, while retaining virtually all of the advantages of da Vinci surgery over traditional laparoscopic surgery.

VIII. ENDOWRIST FAILURES ARE IDENTIFIED BY SURGEONS DURING SURGERY AND MITIGATED; THERE IS NO REASON TO BELIEVE A SERVICED ENDOWRIST WOULD FAIL MORE FREQUENTLY OR DIFFERENTLY THAN A NEW ENDOWRIST

53. During minimally invasive surgery, both laparoscopic and da Vinci instruments – even brand new ones not previously used – can and do fail. This is expected and is not unique to minimally invasive surgery. Failure of instruments is inherent to surgical practice. Surgeons must always be aware of the risk of instrument failure and be ready to take action when such an event occurs.

54. Dealing with instrument failures in this manner is a standard part of training for laparoscopic surgery and a standard part of performing laparoscopic surgery.

55. In the context of a da Vinci surgery, if a da Vinci system component (*e.g.*, the console, patient cart, or robot) fails, or if an EndoWrist malfunctions, surgeons are trained on ways to temporize the situation and correct the issue.

56. With respect to EndoWrists used in da Vinci surgeries, actual instrument failures are almost always identified by the surgeon, not the da Vinci system. The main types of "monitoring" that are performed by the da Vinci system for EndoWrists are basic warnings including those related to movement of the robotic arms being out of range, or when one of the pulley mechanisms within the arm is rotated beyond its acceptable range. The system alerts the surgeon about the operation of the EndoWrist instrument with respect to the patient, such as where a scalpel or forceps is located or if the instruments are in a dangerous or unwarranted position for the patient or particular surgery. Nor does the system provide an alert to the surgeon based on whether a movement of the EndoWrist is or might be causing harm to the patient. Indeed, it is possible for a surgeon to stab a patient or puncture an organ with an EndoWrist instrument if the

surgeon is not careful, and there is nothing in the da Vinci system to monitor or prevent such deviation from acceptable surgical practice.

57. Some typical EndoWrist instrument failures that I have experienced are cable derailment, cable breakage, unintuitive response to commanded movements, and other changes to the movement of the EndoWrist such as changes to range of motion or the scale of the response to commanded movement. These are consistent with the failure modes that Intuitive has identified in its own documentation.[4] Although some failures such as a frayed or broken cable or end effectors are apparent based on the field of view of the camera, most failures are identified in the same basic manner based on surgical experience and intuition regarding the appropriate or expected correlation between a commanded motion at the console and an expected viewed response of the instrument. These failures occur with new, never before used EndoWrist instruments as well with EndoWrists whose use counter reflects previous uses.

58. When a potential or actual EndoWrist failure is identified, the surgery is typically stopped. In rare instances, the failure causes unanticipated bleeding. In such circumstances, there is a need to take corrective action such as sealing a blood vessel prior to assessing the potential malfunction. Such corrective action may be performed with another EndoWrist instrument.

59. Depending on the perceived type of failure and the stage of the surgery, a variety of actions may be taken to check or correct the actual or potential instrument failure, such as exercising the functions of the EndoWrist instrument within the field of view to assess the extent of failure, removing the EndoWrist instrument from its port and manually manipulating the

[4] 30(b)(6) Deposition of Grant Duque at 46:5-51:25; Deposition of Grant Duque at 68:17-72:20; 160:14-169:12.

instrument's input disks, or removing the EndoWrist instrument from its port and replacing the EndoWrist instrument with a same-model instrument.

60. In all such circumstances, the process of diagnosing and correcting the actual or potential instrument failure is typically performed in only a few minutes. I have never seen nor am I aware of any such mitigation procedure harming a patient.

61. In rare cases of EndoWrist failure, additional ports may need to be placed, additional or replacement equipment utilized, or the procedure may need to be converted to another approach including open surgery. Surgeons must always be aware of these risks and be ready to act when an emergency or atypical scenario presents itself in the operating room. I have seen less than 10 cases requiring additional ports or conversion to an open surgery from a da Vinci surgery, and understand such cases are extremely rare. Indeed, over the course of my career involving more than 1,000 da Vinci surgeries, I have never encountered a situation in which a malfunctioning EndoWrist harmed a patient or member of the surgical team, or negatively impacted a successful patient outcome.

62. I have never noticed any difference in the operation or failure rate of different EndoWrist instruments of the same type. Further, I am unaware of any difference in operation or failure rate between EndoWrist instruments based on how many times the instrument has been used. To the extent that a particular EndoWrist instrument has a substantially different response compared to typical EndoWrists instruments, I am confident that I would identify such a change and in that case, I would not use the instrument. Given the nearly identical operation of EndoWrist instruments having different numbers of uses within the usage limits specified by Intuitive, and that EndoWrist failures I am aware of are easily identifiable, there is no reason to believe that an

EndoWrist instrument that has been serviced after expiration of the Intuitive-specified use counter would not operate in the same manner as an EndoWrist whose use counter has not expired.

IX. THE USE COUNTER DOES NOT PROVIDE RELEVANT INFORMATION ABOUT ACTUAL USE, AND IS OF NO VALUE IN ASSESSING LIKELY INSTRUMENT PERFORMANCE

63. Intuitive implements counters with its EndoWrist instruments that are used to dictate and limit the number of times the instrument can be used – sometimes colloquially referred to as the number of "lives" of an instrument. These counters count one use per surgery or procedure. When the counter reaches zero, the EndoWrist will no longer work in a da Vinci system and must be discarded. This is even the case if the EndoWrist is functioning properly and, but for the counter, could still be used.

64. To my knowledge, the counter system is unique to da Vinci products with regard to instruments used by gynecologists. Other multiple-use traditional laparoscopic instruments of which I am aware do not have built in expirations. For virtually every other instrument that I use in my practice except for single-use devices, the decision as to when to replace or service an instrument is left to the discretion of the surgeon, operating room personnel, and hospital administration – not to the manufacturer.

65. The use counter of an EndoWrist instrument does not provide a surgeon any practical, relevant information about the instrument's actual usage, whether in a particular surgery or over the life of the instrument. The counter only informs a surgeon of the number of procedures in which that EndoWrist instrument has been used. It does not inform a surgeon how long the EndoWrist was used in surgery, how it was used, the number of particular movements (*e.g.*, grip, cut, etc.), types of movement (*e.g.*, yaw, pitch, rotation, etc.), types of procedures in which the

EndoWrist was used, the forces it experienced, whether it malfunctioned, or whether it was misused or abused.

66. The EndoWrist use counter does not account for extreme use cases. For example, if an EndoWrist suture cut large needle driver has been used inappropriately or for a long duration, or if an EndoWrist instrument tangled with another EndoWrist instrument (colloquially referred to as a "sword fight"), it may not function well for a surgeon after only a single use and need replacement during a subsequent procedure.

X. SURGEONS REGULARLY USE SERVICED INSTRUMENTS IN SURGERY, INCLUDING LAPAROSCOPIC SURGERY, AND I WOULD BE CONFORTABLE USING SERVICED ENDOWRIST INSTRUMENTS

67. In traditional laparoscopic surgery, cameras, lenses, and laparoscopic instruments are routinely checked for proper function prior to surgery. When deemed needed by staff or physicians, surgical instruments are sent for sharpening, repair, or replacement as necessary. This has been a routine part of surgical practice for at least since I started practicing and has become a standard approach to reduce the expense of unnecessarily purchasing more costly new equipment. Such services are an important component of physicians' and hospitals' attempts to continue to deliver cutting edge care to patients while limiting costs whenever possible. This allows health care practitioners to provide the best possible care to their patients while minimizing costs, thereby making such care available to more people.

68. In cases where refurbished laparoscopic instruments are used, surgeons are not made aware of the instrument status, such as how many times it has been used or whether it has been serviced. As long as the instrument operates safely and to the standards of the surgeon, instruments provided by the hospital team are used without reservation.

69. In general, I am unable to tell the difference between a new surgical instrument and one that has been serviced (*e.g.*, repaired or refurbished).

70. Most surgeons in my experience are not aware of or have only a cursory understanding of the processes used for sterilization and instrument readiness that surgical instruments undergo prior to surgery. As only one part of a multiple-specialty team that strives for the safest surgeries, surgeons trust the procedures implemented by hospitals for supplying well-functioning, sterile instruments. I expect, though have minimal ways of checking prior to the start of surgery, that the instruments I am provided are properly prepared for surgical use. The hospitals where I operate (like other hospitals) use both new and serviced instruments to reduce costs. For example, scissors are sharpened, camera lenses are cleaned or refinished, and retractors with broken or missing parts have components purchased and replaced for use.

71. As a surgeon with extensive experience in traditional laparoscopic surgery, I am comfortable operating with reusable or serviced surgical laparoscopic instruments. I have been doing so for years.

72. Instruments given to me for use during procedures meet the quality standards expected for surgical use in the United States today. Specifically with regard to when and what to service, the hospital or surgery entity is responsible for providing the skill, expertise, and experience to assess when instrument servicing is appropriate and what instruments are serviceable. I am aware that third-party vendors are often utilized as part of this process.

73. As a surgeon with extensive experience in robotic-assisted minimally invasive surgery using the da Vinci system, I also would feel comfortable using repaired or refurbished EndoWrist instruments including ones with reset use counters, for a number of reasons some of which are described in this Report. For example, although the da Vinci system robot and console

may include complex operations and components, the mechanical operating principles of the EndoWrist instruments such as motion of wrists and end effectors are largely unchanged since the introduction of Si instruments, which were introduced at least before I started medical school. As another example, the failure modes of EndoWrist instruments are easily recognizable, such that failures are typically identified and remedied quickly, as sometimes happens even with brand new EndoWrists. As another example, if serviced EndoWrists failed at a greater rate than do EndoWrists that are still within Intuitive's usage limits, this would quickly become widely recognized by surgeons. As another example, the usage counter to my understanding does not actually measure any qualitative information about actual instrument usage.

74. In the course of patient treatment, use of devices and medications in a manner other than for which it was cleared by the FDA (*i.e.*, off-label use) is common. This is the case for certain medical conditions and treatments. Unless serviced EndoWrists proved unsafe or ineffective for patient use, I would be comfortable performing surgeries with serviced EndoWrists. I would be just as comfortable using serviced EndoWrist instruments as I am using serviced laparoscopic and other instruments.

75. I would not have an elevated or particularized concern that a serviced EndoWrist instrument may malfunction during surgery or present an undue risk to a patient, others in the operating room, or the hospital, as compared to an EndoWrist instrument within its initial use count, for the reasons discussed in this report.

Amandeep S. Mahal, MD

December 1, 2022

ATTACHMENT 1

***Curriculum Vitae* of Dr. Amandeep Mahal**

Curriculum Vitae

Amandeep Mahal, MD

Urogynecologist / Sub-Investigator

Affiliated Addresses

Adult & Pediatric Urology P.C.
10707 Pacific Street, Suite 101
Omaha, NE 68114
(402) 397-7989
amahal@adultpediatricuro.com

Adult & Pediatric Urology P.C.
3434 West Broadway, Suite 102
Council Bluffs, IA 51501

Pacific Surgery Center
10707 Pacific Street, Suite 100
Omaha, NE 68114

Education

College:	Saint Mary's College of California Aug 2002-May 2006 Bachelor of Science Major in biochemistry
Medical School:	Creighton University School of Medicine: Omaha, Nebraska August 2006-May 2010 Doctor of Medicine
Residency:	University of Iowa: Iowa City, Iowa July 2010-June 2014 Department of Obstetrics and Gynecology
Fellowship:	Stanford University Hospitals and Clinics July 2014-July 2017 Female Pelvic Medicine and Reconstructive Surgery

Board Certification

January 2016	American Board of Obstetrics and Gynecology
January 2021	American Board of Obstetrics and Gynecology- Female Pelvic Medicine and Reconstructive surgery

Training

September 2020	Good Clinical Practice (GCP) *CITI Program*

Curriculum Vitae

Amandeep Mahal, MD

Urogynecologist / Sub-Investigator

September 2017 Human Subjects Research
CITI Program

Professional Experience

August 2017 – Present Adult Pediatric Urology & Urogynecology, P.C.
Omaha, Nebraska
Urogynecologist/Sub-Investigator

Current Licensure

Nebraska	29590
Iowa	MD-43795

Awards:

2017	Award for pathologic evaluation of vaginal biopsies following laser treatment
2016	Spectrum grant recipient
2015	SPARK seed award recipient for novel drug therapy research
2014	Coulter grant recipient, through SPARK foundation
2014	Grant for the study on novel treatment of interstitial cystitis
2014	Humanism and Excellence in Teaching Award by the Arnold P. Gold Foundation
2013 & 2014	Golden Apple Award winner for Best Resident Teacher for Medical Students
2014	AAGL (American Association of Gynecologic Laparoscopists) and SRS (Society for Reproductive Surgeons) Resident Award for Excellence in Endoscopic Procedures

Memberships:

- Junior Fellow, American College of Obstetricians and Gynecologists
- Masonic Member, Los Banos-Dos Palos Lodge
- American Urologic Association
- American Urogynecologic Society
- Society for Clinical Research Sites (SCRS)
- American Medical Association

Clinical Trial Experience:

2015 – Present Vast experience with the informed consent process

Adult & Pediatric Urology, P.C.

Jul. 2020 – Present A prospective study to assess the efficacy and safety of the BlueWind RENOVA iStim™ System for the treatment of patients diagnosed with overactive bladder
Sub-Investigator

Curriculum Vitae

Amandeep Mahal, MD

Urogynecologist / Sub-Investigator

May 2020 – Present	Randomized, Single-blind, Sham-controlled, Multicenter, Prospective Study to Evaluate Safety and Effectiveness of the Hologic's trigone radiofrequency ablation device for the treatment of urgency urinary incontinence. *Sub-Investigator*
Feb. 2020 – Present	Clinical Study of Implantable Sacral Nerve Stimulation (SNS) System in Patients with Symptoms of Overactive Bladder *Sub-Investigator*
Mar. 2019 – Sep. 2020	Phase 2 Study Evaluating the Efficacy an Safety of Botox Intravesical Instillation in Patients w/ OAB and Urinary Incontinence *Sub- Investigator*
Nov. 2018 – Dec 2019	To assess the effect of 3 different amplitude settings on urinary urge incontinence with the InterStim II system *Sub- Investigator*
Sep. 2018 – Present	Pivotal Study of Subcutaneous Tibial Nerve Stimulation with eCoin for Urgency Urinary Incontinence *Sub-Investigator*
Sep. 2018 – Present	Multi-center, Prospective, Randomized, Controlled, Non-Inferiority, Clinical Trial of Chronic Afferent Nerve Stimulation (CAN-Stim) of the Tibial Nerve versus Sacral Nerve Stimulation (SNS) in the treatment of Urinary Urgency Incontinence resulting from Refractory Overactive Bladder (OAB) *Sub-Investigator*
May 2018 – Jul. 2020 and Efficacy	Viveve Geneveve Treatment of the Vaginal Introitus to Evaluate Safety *Sub-Investigator*
Apr. 2018 – Mar. 2019	An International Phase 3, Randomized, Double-Blind, Placebo-and Active (Tolterodine)-Controlled Multicenter Study to Evaluate the Safety and Efficacy of Vibegron in Patients with Symptoms of Overactive Bladder *Sub-Investigator*
Jan. 2018 – Nov. 2018	A Phase 2b, Multicenter, Randomized, Double-blind, Placebo-Controlled, parallel Group Study to Evaluate the Efficacy and Safety or Oral Solabegron Immediate Release Tablets in the Treatment of Overactive Bladder (OAB) in Adult Female Subjects *Sub-Investigator*

Curriculum Vitae

Amandeep Mahal, MD

Urogynecologist / Sub-Investigator

Oct. 2017 – Nov. 2020	A Post-Market Evaluation of the Altis® Single Incision Sling System versus Transobturator or Retropubic Mesh Sling in the Treatment of Female Stress Urinary Incontinence (Control Arm) *Sub-Investigator*
Oct. 2017 – July 2018	A Multicenter, Randomized, Double-Blind, Placebo-Controlled, Parallel-Group Study to Evaluate an Alternative Injection Paradigm for OnabotulinumtoxinA (BOTOX®) in the Treatment of Overactive Bladder in Patients with Urinary Incontinence *Sub-Investigator*
Oct. 2017 – Nov. 2020	Transvaginal Mesh versus Native Tissue Repair for Treatment of Pelvic Organ Prolapse *Sub-Investigator*
Oct. 2017 – July. 2018	A Prospective Clinical Trial to Assess the Feasibility of the Senza™ Spinal Cord Stimulation (SCS) System to Stimulate the Sacral Nerve for the Treatment of Overactive Bladder *Sub-Investigator*
Oct. 2017 – Aug. 2018	A 12-Week, Randomized, Multi-Center, Double-Blind, Placebo-Controlled, 3-Arm, Parallel-Group, Phase 3 Trial to Evaluate the Efficacy and Safety of 2 Doses of AQX-1125 Targeting the SHIP1 Pathway in Subjects with Interstitial Cystitis/Bladder Pain Syndrome Followed by an Extension Period *Sub-Investigator*
Oct. 2017 – Aug. 2020	Axonics Sacral Neuromodulation System for Urinary Urgency Incontinence Treatment *Sub-Investigator*
Stanford	
2017	Research trial for pathologic evaluation of vaginal biopsies following laser treatment *Principle Investigator*
2015 - 2017	Study to Evaluate the Efficacy, Safety, and Tolerability of Mirabegron in Older Adult Subjects with Overactive Bladder (OAB) *Sub-Investigator*
2014 – 2017	Research trial for characterization of novel treatment for interstitial cystitis

Curriculum Vitae

Amandeep Mahal, MD

Urogynecologist / Sub-Investigator

Principle Investigator

Publications:

- Dobberfuhl AD, Mahal A, Dallas KB, Choi KM1, Comiter CV, Elliott CS. (2018). Statewide Success of Staged Sacral Neuromodulation for the Treatment of Urinary Complaints in California (2005-2011). Female Pelvic Med Reconstr Surg. 2018 Jul 27. doi: 10.1097/SPV.0000000000000605. and 2020;26(7):437-442.

- Mahal, A., Young-Lin, N., Dobberfuhl, A., Estes, J., & Comiter, C. V. (2018). Peroxisome proliferator-activated receptor gamma agonist as a novel treatment for interstitial cystitis: A rat model. Investigative and Clinical Urology, 59(4), 257–262. http://doi.org/10.4111/icu.2018.59.4.257

- Ripperda, CM; Kowalski, JT; Chaudhry, ZQ; Mahal, AS; Lanzer, J; Noor, N; Good, MM; Hynan, LS; Jeppson, PC; Rahn, DD (2016). Predictors of early postoperative voiding dysfunction and other complications following a midurethral sling. Am J Obstet Gynecol. 2016 Jun 16 : S0002-9378(16)30338-6. Published online 2016 Jun 16. doi: 10.1016/j.ajog.2016.06.010

- Mahal, A; Rhoads, K; Elliott, C; Sokol, E. Inappropriate oophorectomy at time of benign premenopausal hysterectomy. The Journal of The North American Menopause Society. 2017 August; 24 (8): 947–953
- Suharwardy, S; Mahal, AS; Wieskopf KM; Rogo-Gupta, L. Glomus Tumor Excision with Clitoral Preservation. Journal of Lower Genital Tract Disease. 2016 April; 20(2):e20-21

- Dickerhoff LA, Mahal AS, Stockdale C, Hardy-Fairbanks A. Management of Cesarean Section Scar Pregnancy in the Second Trimester; a report of three cases. Journal of Reproductive Medicine. 2015 May-Apr; 60 (3-4): 165-8.

- Mahal AS, Bradley CS. Necrotizing Postsurgical infection complicating midurethral sling procedure with unrecognized cystotomy. Female Pelvic Medicine and Reconstructive Surgery. 2012 May; 18(3): 183-185. PMID: 22543774

- Mahal, Amandeep, Gupta Pratek, Hunter William, Sugimoto Jeffrey. Type C Quadricuspid Aortic Valve with Aortic Stenosis and Insufficiency. Internet Journal of Cardiology. 2012. http://www.ispub.com/journal/the-internet-journal-of-cardilogy/volume-8-number-1/rare-type-c-qyadrucysoud-aortic-valve-presenting-with-aortic-stenosis-and-aortic-insufficiency.html#sthash.5mpuohJi.dpbs.

- Beyond the Abstract: Necrotizing Infections with Midurethral Sling. Epub-Urotoday.com

- Iowa Junior Fellow Activity. Proceedings in Obstetrics and Gynecology. Vol 2 Iss 3. http://ir.uiowa.edu/pog/vol2/iss3/11/

Curriculum Vitae
Amandeep Mahal, MD
Urogynecologist / Sub-Investigator

- Events around District VI. E-newsletter published through Junior fellow Congress Advisory Council. 2013 Junior Fellow Update. The District VI Monitor E-pub- http://www.acog.org/About ACOG/ACOG Departments/District_Newsletters/District_VVMarch_2014

Posters Presentations

2008 Novel Use of Lux Gene Reporter System. Saint Mary's College of California Research Day

2010 Multiple Mortality and Morbidity presentations, including presentations on Lotus Birth, Supracervical hysterectomy, and Anal Sphincteroplasty

2012 Accuracy of2-D vs. 3-D Ultrasound in Measurement of Cervical Length. Central Association of Obstetrics and Gynecology Annual Meeting

2013 Persistent Post-Operative Granulation Tissue following Vaginal Prolapse Repair. Society of Gynecologic Surgeons Annual Scientific meeting

2014 Do Patient Characteristics Impact The Relationship Between Vaginal Bulge Symptoms and anatomic prolapse? Oral presentation. American Urogynecologic Society/ International Urogynecological Association Annual Meeting

2015 Novel injection systems for murine stress incontinence models. Poster presentation. American Urologic Association Annual Meeting

2015 Unilateral versus bilateral sacral neural modulation for incontinence: Single center quality improvement evaluation. Poster presentation. Western Section of American Urologic Association Annual meeting

2015 Stem cell injection system for murine incontinence model. Moderated oral poster. American Urogynecologic Society annual scientific meeting.

2016 Predictors of Early Post-Operative Voiding Dysfunction and other complications following Mid-Urethral Sling: a Multicentered Review from the Fellows Research Network. Society of Gynecologic Surgeons Annual Scientific Meeting. Oral poster

2016 Rates of inappropriate Oophorectomy at the Time of Benign Hysterectomy. Society of Gynecologic Surgeons Annual Scientific Meeting. Oral Presentation
Awarded Best Fellow Research Paper

Teaching Positions and Presentations

Curriculum Vitae

Amandeep Mahal, MD

Urogynecologist / Sub-Investigator

2014	History and state of prophylactic oophorectomy. Stanford FPMRS conference
2014	Sacral Nerve Stimulator treatment for Fecal Incontinence. Stanford FPMRS conference
2015	Urethral reconstruction and Diverticula Treatment. Stanford Urology Grand Rounds
2015	Vulvar Vaginal Disease for the Urogynecologist. Stanford FPMRS conference
2014-16	Pelvic organ prolapse for medical students: what you need to know. Presentation given to every 3rd year medical student block at Stanford Hospitals and Clinics
2014-16	Urinary Incontinence for Medical Students: What you need to know. Presentation given to every 3rd year medical student block at Stanford Hospitals and Clinics
2016	Urodynamics Review for Creog. Resident Teaching OBGYN
2016	LUTS following GYN surgery. Stanford FPMRS conference
2016	OBGYN resident mock oral session. Session instructor
2016	GU injury in GYN surgery. Resident Teaching OBGYN
2018	Adjunct Professor at Creighton University School of Medicine
2021	Adjunct Professor at the University of Nebraska, Urology and OBGYN departments
2022	American Medical Association Alternate Delegate for Nebraska - Safety committee

ATTACHMENT 2

Materials Considered

1. AHS_MGMT-INTUITIVE_0000313-23
2. ALPIN00001-05
3. Intuitive-00002201-501
4. Intuitive-00002502-876
5. Intuitive-00044523
6. Intuitive-00044524-26
7. Intuitive-00286314-28
8. Intuitive-00544199-214
9. Intuitive-00552744
10. Intuitive-00552745-59
11. Intuitive-02066979-7059
12. REBOTIX060982
13. REBOTIX060986-89
14. REBOTIX060990-92
15. REBOTIX060993-1007
16. REBOTIX068403
17. REBOTIX068404-18
18. REBOTIX145274-79
19. REBOTIXI62404-24
20. REBOTIX175327
21. Restore-00001538-78
22. Restore-00002095-98
23. Restore-00003404
24. Restore-00003405-26
25. Restore-00005217
26. Restore-00005218-19
27. Restore-00005580-82
28. Restore-00006160-63
29. Restore-00007127
30. Restore-00007128-39
31. Restore-00007938-41
32. Restore-00007942-46
33. Restore-00007947-75
34. Restore-00007976-79
35. Restore-00007980
36. Restore-00022923

37. Restore-00022927
38. Restore-00027409
39. Restore-00027410-20
40. Restore-00032120-23
41. Restore-00034134-42
42. Restore-00060361
43. Restore-00060362-64
44. Restore-00060365-86
45. Restore-00067983-84
46. Expert Report of Dr. John Bomalaski dated July 26, 2021
47. Expert Report of Dr. John Bomalaski dated August 20, 2021
48. Complaint, *Surgical Instrument Service Co., Inc. v. Intuitive Surgical, Inc.*, Case No. 3:21-CV-03496-VC (N.D. Cal.)
49. 30(b)(6) Deposition of Grant Duque dated November 8, 2022
50. Deposition of Grant Duque dated November 8, 2022
51. Bingmer et al., *Decline of Open Surgical Experience for General Surgery Residents*, Springer Nature, May 29, 2019, https://doi.org/10.1007/s00464-019-06881-0.
52. Sheetz at al., *Trends I the Adoption of Robotic Surgery for Common Surgical Procedures*, Journal of American Medicine, Jan. 10, 2020, https://jamanetwork.com/journals/jamanetworkopen/fullarticle/2758472.